

FACT SHEET

M tuberculosis Amplification (GeneXpert MTB-RIF) 3530

Last Updated: 5/8/15

Mycobacterium Tuberculosis Amplification test (Cepheid GeneXpert MTB-RIF) is a qualitative, real-time polymerase chain reaction (PCR) method for the in vitro diagnostic detection of Mycobacterium tuberculosis complex DNA and rifampin resistance in acid-fast bacilli (AFB) smear-positive and smear-negative respiratory specimens

Acceptable Specimens:

- Sputum and/or Concentrated Digested Sputum minimum 1 ml
- Bronchial Washings/Aspirate minimum 1 ml

Transport and Holding times

- Store specimen(s) at 2-8 C
- Maximum Holding time 72 hours.

Interpretation:

- Samples may be MTB-RIF negative and M. tuberculosis complex culture positive. This condition may be caused by inhibitory substances such as lectins, or the low numbers of the M. tuberculosis in the sample.
- The MTB-RIF test is not indicated for use with specimens from patients being treated with antituberculous agents to determine bacteriologic cure or to monitor response to such therapy.
- Specimens that are grossly bloody should not be tested with the MTB/RIF test; blood may cause nonspecific positivity in the MTB/RIF The performance of the Xpert MTB/RIF Assay has not been evaluated with samples from pediatric patients.
- Assay interference may be observed in the presence of Lidocaine (>20% v/v), mucin (>1.5% w/v), Ethambutol (>5 µg/mL), Guaifenesin (>2.5 mg/mL), Phenylephrine (>25% v/v), or tea tree oil (>0.008% v/v).
- A positive test does not necessarily indicate the presence of viable organisms.

Sensitivity has been reported as 90.9-98.4 % A negative test does not exclude the possibility of isolating an M. tuberculosis complex organism from the specimen. The efficacy of this test has not been demonstrated other clinical specimens (e.g., blood, CSF, tissue, urine, or stool).

Specificity has been reported to vary from 89 to 100% in various studies.

Please contact Stacy Evans 805-781-5509, sevens@co.slo.ca.us, or Director Dr James Beebe 805-781-5512, jbeebe@co.slo.ca.us, if you would like more information on this test.



San Luis Obispo County Public Health Laboratory

Phone: (805) 781-5507 Fax: (805) 781-1023 www.sloPublicHealth.org/lab
2191 Johnson Ave., San Luis Obispo, CA 93401
Laboratory Hours: Monday – Friday, 8:00am – 5:00pm